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Award Number: W81XWH-11-1-0815

TITLE: Pathophysiology of Post Amputation Pain

PRINCIPAL INVESTIGATOR: Dr. R. Norman Harden

CONTRACTING ORGANIZATION: Rehabilitation Institute of Chicago

REPORT DATE: 10/11/2012

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

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| <b>REPORT DOCUMENTATION PAGE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                         |                                 |                                             | <i>Form Approved</i><br><i>OMB No. 0704-0188</i>           |                                                   |
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| <b>1. REPORT DATE</b><br>11 October 2012                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                         | <b>2. REPORT TYPE</b><br>Annual |                                             | <b>3. DATES COVERED</b><br>26September2011-25September2012 |                                                   |
| <b>4. TITLE AND SUBTITLE</b><br>Pathophysiology of Post Amputation Pain                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                         |                                 |                                             | <b>5a. CONTRACT NUMBER</b>                                 |                                                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                         |                                 |                                             | <b>5b. GRANT NUMBER</b><br>W81XWH-11-1-0815                |                                                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                         |                                 |                                             | <b>5c. PROGRAM ELEMENT NUMBER</b>                          |                                                   |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                         |                                 |                                             | <b>5f. WORK UNIT NUMBER</b>                                |                                                   |
| <b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b><br><br>Rehabilitation Institute of Chicago<br>446 E. Ontario St. Ste.1011<br>Chicago, IL 60611                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                         |                                 |                                             | <b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>            |                                                   |
| <b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b><br>U.S. Army Medical Research and Materiel Command<br>Fort Detrick, Maryland 21702-5012                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                         |                                 |                                             | <b>10. SPONSOR/MONITOR'S ACRONYM(S)</b>                    |                                                   |
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| <b>12. DISTRIBUTION / AVAILABILITY STATEMENT</b><br>Approved for Public Release; Distribution Unlimited                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                         |                                 |                                             |                                                            |                                                   |
| <b>13. SUPPLEMENTARY NOTES</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                         |                                 |                                             |                                                            |                                                   |
| <b>14. ABSTRACT</b><br><br>This study is being done because post amputation pain (PAP) is common, yet very little is known about the causes of this pain. The purpose of this study is to see how PAP affects the body and brain by using sensory testing (such as pinprick testing), taking pictures of your brain (using a functional magnetic resonance imaging (fMRI) machine) and biomedical interventions (such as an injection of pain medicine). We hope that by learning the causes of PAP, we can help future amputees.                                                                                                                                                                                                                                                                                                                                                                                                                         |                         |                                 |                                             |                                                            |                                                   |
| <b>15. SUBJECT TERMS</b><br>Phantom pain, Phantom sensation, Post amputation pain                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                         |                                 |                                             |                                                            |                                                   |
| <b>16. SECURITY CLASSIFICATION OF:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                         |                                 | <b>17. LIMITATION OF ABSTRACT</b><br><br>UU | <b>18. NUMBER OF PAGES</b><br><br>23                       | <b>19a. NAME OF RESPONSIBLE PERSON</b><br>USAMRMC |
| <b>a. REPORT</b><br>U                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>b. ABSTRACT</b><br>U | <b>c. THIS PAGE</b><br>U        |                                             |                                                            | <b>19b. TELEPHONE NUMBER</b> (include area code)  |

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## **INTRODUCTION:**

This study is being done because post amputation pain (PAP) is common, yet very little is known about the causes of this pain. The purpose of this study is to see how PAP affects the body and brain by using sensory testing (such as pinprick testing), taking pictures of your brain (using a functional magnetic resonance imaging (fMRI) machine) and biomedical interventions (such as an injection of pain medicine). We hope that by learning the causes of PAP, we can help future amputees.

## **BODY:**

During this year our experiment consisted of submitting all study materials and protocol for approval and working out the logistics to begin the experiment. The goal was to be ready to start upon immediate approval of the IRB. This included working with the team to get all supplies and materials needed for the injection, the fMRI, and all of the other testing and forms to perform the experiment. Recruitment techniques were also heavily discussed such as using flyers, past participants from other studies, and an ad on the CTA. Equipment such as the electrical stimulus and our temperature testing with the Medoc was tested to ensure that machines could be used in various settings. Our protocol was completed and accepted by both Northwestern University and DOD. While waiting for the board to approve it adjustments to the study team were made including the addition of a biostatistics expert. Upon the approval of the IRB coordination of various teams was needed to create a schedule that would work. The randomization of participant's tool and the blind was created and maintained to be kept in a safe area. A clinical trials account was set up as well. Phone screenings began and participants were scheduled. As subjects went through each visit it was realized that there would need to be an adjustment made to the protocol and consent to allow more funds for the taxi cab ride to and from Northwestern's MRI Suite to the Rehabilitation Institute of Chicago's Spine and Sports Recreation Center where the injection is administered. Traffic is unpredictable in Chicago and often the cab rides cost more than the allotted budget currently allows. In turn there is not enough money for a proper lunch which is necessary since the study lasts about 7 hours for the second visit. In conclusion, the protocol does not prospectively allow interim data analysis at this stage.

**KEY RESEARCH ACCOMPLISHMENTS:** Bulleted list of key research accomplishments emanating from this research

- IRB approval
- Recruitment techniques solidified
- Coordination of all teams and equipment to begin experiment
- Recruited subjects
- 14 phone screenings completed
- 3 subjects have finished the whole protocol

- 6 enrolled subjects

**REPORTABLE OUTCOMES:** N/A (it is too early in the protocol to begin an interim analysis but this will be a future goal).

**CONCLUSION:** As reported earlier it is too early in the protocol to begin an interim analysis but this will be a future goal. We will continue to recruit subjects and in the future will perform an interim analysis.

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## APPENDICES:

### CES-D 10

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

0= Rarely or none of the time (less than 1 day)

1= Some or a little of the time (1-2 days)

2= Occasionally or a moderate amount of time (3-4 days)

3= Most or all of the time (5-7 days)

|                                                           |   |   |   |   |
|-----------------------------------------------------------|---|---|---|---|
| 1. I was bothered by things that usually don't bother me. | 0 | 1 | 2 | 3 |
|-----------------------------------------------------------|---|---|---|---|

|                                                       |   |   |   |   |
|-------------------------------------------------------|---|---|---|---|
| 2. I had trouble keeping my mind on what I was doing. | 0 | 1 | 2 | 3 |
|-------------------------------------------------------|---|---|---|---|

|                      |   |   |   |   |
|----------------------|---|---|---|---|
| 3. I felt depressed. | 0 | 1 | 2 | 3 |
|----------------------|---|---|---|---|

|                                                |   |   |   |   |
|------------------------------------------------|---|---|---|---|
| 4. I felt that everything I did was an effort. | 0 | 1 | 2 | 3 |
| 5. I felt hopeful about the future.            | 0 | 1 | 2 | 3 |
| 6. I felt fearful.                             | 0 | 1 | 2 | 3 |
| 7. My sleep was restless.                      | 0 | 1 | 2 | 3 |
| 8. I was happy.                                | 0 | 1 | 2 | 3 |
| 9. I felt lonely.                              | 0 | 1 | 2 | 3 |
| 10. I could not get "going."                   | 0 | 1 | 2 | 3 |

### NRS Data Collection Form

| Time | Event Description                        | Phantom Limb Pain<br>NRS Rating 0-10 | Residual Limb Pain<br>NRS Rating 0-10 |
|------|------------------------------------------|--------------------------------------|---------------------------------------|
|      | Pre-Injection                            |                                      |                                       |
|      | Injection<br>Type: Neuroma or Symp Block | n/a                                  | n/a                                   |
|      | 15 min post-injection                    |                                      |                                       |
|      | 1 hour post-injection                    |                                      |                                       |
|      | 2 hours post-injection                   |                                      |                                       |
|      | 3 hours post-injection                   |                                      |                                       |
|      | 4 hours post-injection                   |                                      |                                       |
|      | 5 hours post-injection                   |                                      |                                       |
|      | 6 hours post-injection                   |                                      |                                       |
|      | 7 hours post-injection                   |                                      |                                       |
|      |                                          |                                      |                                       |
|      |                                          |                                      |                                       |
|      |                                          |                                      |                                       |
|      |                                          |                                      |                                       |
|      |                                          |                                      |                                       |

## PASS

Individuals who experience pain develop different ways to respond to that pain. We would like to know what you do and what you think about when in pain. Please use the rating scale below to indicate how often you engage in each of the following thoughts or activities. Circle any number from 0 (NEVER) to 5 (ALWAYS) for each item.

|     |                                                                                                | <u>NEVER</u> |   |     | <u>ALWAYS</u> |   |  |
|-----|------------------------------------------------------------------------------------------------|--------------|---|-----|---------------|---|--|
| 1.  | I think that if my pain gets too severe, it will never decrease .....                          | 0            | 1 | 2 3 | 4             | 5 |  |
| 2.  | When I feel pain I am afraid that something terrible will happen.....                          | 0            | 1 | 2 3 | 4             | 5 |  |
| 3.  | I go immediately to bed when I feel severe pain .....                                          | 0            | 1 | 2 3 | 4             | 5 |  |
| 4.  | I begin trembling when engaged in activity that increases pain.....                            | 0            | 1 | 2 3 | 4             | 5 |  |
| 5.  | I can't think straight when I am in pain .....                                                 | 0            | 1 | 2 3 | 4             | 5 |  |
| 6.  | I will stop any activity as soon as I sense pain coming on .....                               | 0            | 1 | 2 3 | 4             | 5 |  |
| 7.  | Pain seems to cause my heart to pound or race.....                                             | 0            | 1 | 2 3 | 4             | 5 |  |
| 8.  | As soon as pain comes on I take medication to reduce it.....                                   | 0            | 1 | 2 3 | 4             | 5 |  |
| 9.  | When I feel pain I think that I may be seriously ill.....                                      | 0            | 1 | 2 3 | 4             | 5 |  |
| 10. | During painful episodes it is difficult for me to think of anything else besides the pain..... | 0            | 1 | 2 3 | 4             | 5 |  |
| 11. | I avoid important activities when I hurt.....                                                  | 0            | 1 | 2 3 | 4             | 5 |  |
| 12. | When I sense pain I feel dizzy or faint .....                                                  | 0            | 1 | 2 3 | 4             | 5 |  |
| 13. | Pain sensations are terrifying .....                                                           | 0            | 1 | 2 3 | 4             | 5 |  |
| 14. | When I hurt I think about the pain constantly.....                                             | 0            | 1 | 2 3 | 4             | 5 |  |
| 15. | Pain makes me nauseous (feel sick) .....                                                       | 0            | 1 | 2 3 | 4             | 5 |  |
| 16. | When pain comes on strong I think I might become paralyzed or more disabled .....              | 0            | 1 | 2 3 | 4             | 5 |  |



|     |                                                                      |   |   |     |   |   |
|-----|----------------------------------------------------------------------|---|---|-----|---|---|
| 17. | I find it hard to concentrate when I hurt .....                      | 0 | 1 | 2 3 | 4 | 5 |
| 18. | I find it difficult to calm my body down after periods of pain ..... | 0 | 1 | 2 3 | 4 | 5 |
| 19. | I worry when I am in pain.....                                       | 0 | 1 | 2 3 | 4 | 5 |
| 20. | I try to avoid activities that cause pain.....                       | 0 | 1 | 2 3 | 4 | 5 |

**CES-D 10**

Below is a list of the ways you might have felt or behaved. Please tell me how often you have felt this way during the past week.

0= Rarely or none of the time (less than 1 day)

1= Some or a little of the time (1-2 days)

2= Occasionally or a moderate amount of time (3-4 days)

3= Most or all of the time (5-7 days)

|                                                           |   |   |   |   |
|-----------------------------------------------------------|---|---|---|---|
| 1. I was bothered by things that usually don't bother me. | 0 | 1 | 2 | 3 |
| 2. I had trouble keeping my mind on what I was doing.     | 0 | 1 | 2 | 3 |
| 3. I felt depressed.                                      | 0 | 1 | 2 | 3 |
| 4. I felt that everything I did was an effort.            | 0 | 1 | 2 | 3 |
| 5. I felt hopeful about the future.                       | 0 | 1 | 2 | 3 |
| 6. I felt fearful.                                        | 0 | 1 | 2 | 3 |
| 7. My sleep was restless.                                 | 0 | 1 | 2 | 3 |

|                 |   |   |   |   |
|-----------------|---|---|---|---|
| 8. I was happy. | 0 | 1 | 2 | 3 |
|-----------------|---|---|---|---|

|                   |   |   |   |   |
|-------------------|---|---|---|---|
| 9. I felt lonely. | 0 | 1 | 2 | 3 |
|-------------------|---|---|---|---|

|                              |   |   |   |   |
|------------------------------|---|---|---|---|
| 10. I could not get “going.” | 0 | 1 | 2 | 3 |
|------------------------------|---|---|---|---|

| <b>Time</b> | <b>Event Description</b>                 | <b>Phantom Limb Pain<br/>NRS Rating 0-10</b> | <b>Residual Limb Pain<br/>NRS Rating 0-10</b> |
|-------------|------------------------------------------|----------------------------------------------|-----------------------------------------------|
|             | Pre-Injection                            |                                              |                                               |
|             | Injection<br>Type: Neuroma or Symp Block | n/a                                          | n/a                                           |
|             | 15 min post-injection                    |                                              |                                               |
|             | 1 hour post-injection                    |                                              |                                               |
|             | 2 hours post-injection                   |                                              |                                               |
|             | 3 hours post-injection                   |                                              |                                               |
|             | 4 hours post-injection                   |                                              |                                               |
|             | 5 hours post-injection                   |                                              |                                               |
|             | 6 hours post-injection                   |                                              |                                               |
|             | 7 hours post-injection                   |                                              |                                               |
|             |                                          |                                              |                                               |
|             |                                          |                                              |                                               |
|             |                                          |                                              |                                               |
|             |                                          |                                              |                                               |
|             |                                          |                                              |                                               |

## PASS

Individuals who experience pain develop different ways to respond to that pain. We would like to know what you do and what you think about when in pain. Please use the rating scale below to indicate how often you engage in each of the following thoughts or activities. Circle any number from 0 (NEVER) to 5 (ALWAYS) for each item.

|     |                                                                                                | <u>NEVER</u> |   |     | <u>ALWAYS</u> |   |
|-----|------------------------------------------------------------------------------------------------|--------------|---|-----|---------------|---|
| 21. | I think that if my pain gets too severe, it will never decrease .....                          | 0            | 1 | 2 3 | 4             | 5 |
| 22. | When I feel pain I am afraid that something terrible will happen.....                          | 0            | 1 | 2 3 | 4             | 5 |
| 23. | I go immediately to bed when I feel severe pain .....                                          | 0            | 1 | 2 3 | 4             | 5 |
| 24. | I begin trembling when engaged in activity that increases pain.....                            | 0            | 1 | 2 3 | 4             | 5 |
| 25. | I can't think straight when I am in pain .....                                                 | 0            | 1 | 2 3 | 4             | 5 |
| 26. | I will stop any activity as soon as I sense pain coming on .....                               | 0            | 1 | 2 3 | 4             | 5 |
| 27. | Pain seems to cause my heart to pound or race.....                                             | 0            | 1 | 2 3 | 4             | 5 |
| 28. | As soon as pain comes on I take medication to reduce it.....                                   | 0            | 1 | 2 3 | 4             | 5 |
| 29. | When I feel pain I think that I may be seriously ill.....                                      | 0            | 1 | 2 3 | 4             | 5 |
| 30. | During painful episodes it is difficult for me to think of anything else besides the pain..... | 0            | 1 | 2 3 | 4             | 5 |
| 31. | I avoid important activities when I hurt .....                                                 | 0            | 1 | 2 3 | 4             | 5 |
| 32. | When I sense pain I feel dizzy or faint .....                                                  | 0            | 1 | 2 3 | 4             | 5 |
| 33. | Pain sensations are terrifying .....                                                           | 0            | 1 | 2 3 | 4             | 5 |
| 34. | When I hurt I think about the pain constantly.....                                             | 0            | 1 | 2 3 | 4             | 5 |
| 35. | Pain makes me nauseous (feel sick) .....                                                       | 0            | 1 | 2 3 | 4             | 5 |
| 36. | When pain comes on strong I think I might become paralyzed or more disabled .....              | 0            | 1 | 2 3 | 4             | 5 |
| 37. | I find it hard to concentrate when I hurt .....                                                | 0            | 1 | 2 3 | 4             | 5 |

|     |                                                                      |   |   |     |   |   |
|-----|----------------------------------------------------------------------|---|---|-----|---|---|
| 38. | I find it difficult to calm my body down after periods of pain ..... | 0 | 1 | 2 3 | 4 | 5 |
| 39. | I worry when I am in pain.....                                       | 0 | 1 | 2 3 | 4 | 5 |
| 40. | I try to avoid activities that cause pain.....                       | 0 | 1 | 2 3 | 4 | 5 |

**SUPPORTING DATA:** N/A (it is too early in the protocol to begin an interim analysis but this will be a future goal).